REMARKS

Claims 1-52 are now pending in the application.

In the Office Action, the Examiner stated that Applicant's previous arguments with respect to the allowability of claims 1-52 had been considered but were moot in view of the new ground(s) of rejection. Applicant notes, however, that only claims 1-2, 5-7, 10, 20, 23-35, and 30 are the subject of a new ground of rejection. Accordingly, Applicant's previous arguments regarding the allowability of claims 3-4, 8-9, 11-19, 21-22, 26-29, and 31-52 are not moot and should have been addressed in the Office Action. For the Office's convenience, those arguments are repeated here, along with additional arguments responsive to the Office's new grounds of rejection.

In view of these earlier arguments and the new arguments included herewith, Applicant believes that all claims are in condition for allowance over the cited art.

Rejections of the Claims under 35 USC § 103:

In the Office Action, the Examiner rejected claims 1, 2, 5-7, 10, 20, 23-25, and 30 as being obvious over Sterman et al. (U.S. Patent No. 5,814,097). Applicant believes that the claims are allowable over Sterman et al., as set forth below.

As a first matter, Applicant notes that the new 103 rejection over Sterman et al. is substantially similar to the earlier 102 rejection under Sterman et al. The Office makes reference to a discussion in Sterman et al., namely at columns 15-16, with respect to Fig. 34a. Applicant notes that the discussion in Sterman at columns 15-16 is directed to Fig. 3, and not to Fig. 34a. (The discussion of Fig. 34a takes place at columns 17-18 of Sterman.) The device depicted in Fig. 3 and discussed in columns 15-16 is a cardiopulmonary bypass system (including elements 70, 78) in conjunction with an aortic occlusion catheter (element 82) for arresting the heart. (Sterman, col. 15, lines 18-27 and 53-56.) The devices depicted in Figs. 26-34 are "exemplary embodiments of an aortic partitioning system" (Sterman, col. 17, lines 53-55), used to isolate the right atrium and for venous drainage. The cited portions of Sterman are thus directed toward a system for

controlling blood flow during a surgical procedure. As discussed in greater detail below, Sterman is different in purpose and structure from the claimed invention and, as such, is not seen as providing any support for a Section 103 obviousness rejection.

Independent claim 1 includes the limitation that the retrograde probe distal portion is positioned adjacent the antegrade probe distal portion. While Fig. 34a of Sterman depicts two probes, there is no teaching or suggestion that the two probes are placed adjacent to each other. Instead, for Figs. 26-34 Sterman teaches that the balloon 414 of the one catheter is adapted to occlude the superior vena cava 416, and the balloon 415 of the other catheter is adapted to occlude the inferior vena cava 417. (Col. 18, lines 9-14, 38-43.) The catheter ends are thus on opposing sides of the right atrium 422, and are not adjacent as required by claim 1. The cited device from Sterman et al. is an endovascular aortic partitioning system, with the partition defined by the space between the ends of the respective probes. (See, e.g., fig. 34a; col. 17, line 53 to col. 18, line 53.) Placing the catheter ends of Sterman adjacent to each other would result in no partition being created, and would thus destroy the utility of Sterman to isolate the right atrium. Accordingly, Sterman teaches away from the invention of claim 1. As the Office is aware, a reference that teaches away from a claimed invention is not an appropriate basis for a Section 103 obviousness rejection.

Independent claim 30 similarly includes the limitation that the retrograde probe distal portion is positioned adjacent the antegrade probe distal portion, and is thus allowable in so far as claim 1 is allowable. Claim 30 further recites that the probes are antegrade and retrograde, respectively, to the tissue being repaired. While Sterman has tissue, namely the atrium walls, the catheters of Sterman are not repairing the atrium but are instead merely providing blood flow during a period of cardiac arrest. Accordingly, claim 30 is allowable over Sterman.

Dependent claims 2, 5-7, 10, 20, and 23-25 depend from claim 1, and are thus allowable insofar as claim 1 is allowable. Moreover, many of these dependent claims include additional limitations which can further distinguish them over Sterman.

For example, claim 2 recites the antegrade probe and retrograde probe placed over a common guidewire. By contrast, Sterman has no teaching or suggestion of two probes

sharing a common guidewire. Sterman only makes two brief references to guidewires, and the guidewires are never depicted in the figures. The only references to guidewires are where Sterman states that an aortic occlusion catheter "is advanced, usually over a guidewire (not shown) . . . " (Sterman, col. 15, lines 56-57), and that a retroperfusion catheter can be "positioned, usually over a guidewire (not shown) . . . ." (Sterman, col. 16, lines 23-24). Nowhere does Sterman teach or suggest that antegrade and retrograde probes might share a common guidewire. In the absence of such teaching or suggestion, there is no basis for a Section 103 rejection.

Claim 2 further includes an antegrade guidewire port and a retrograde guidewire port in alignment. No such alignment is taught by Sterman. The Office has asserted that Fig. 34a of Sterman discloses catheters in alignment. As a first matter, the view of Fig. 34a is not believed to be to scale, and the purported depiction of axial alignment is believed to be the result of convenience to the draftsman. The view is also a two-dimensional view from only one side, which in the absence of further figures and/or description is not believed to teach alignment of the two catheters in real (i.e., 3-dimensional) space. It is particularly notable that such alignment is nowhere referenced in Sterman. The Sterman specification with respect to Figs. 26-34 describes the balloon 414 of the one catheter occluding the superior vena cava 416, and the balloon 415 of the other catheter occluding the inferior vena cava 417. (Col. 18, lines 9-14, 38-43.) Sterman's catheters 411b and 411c, as depicted in Fig. 34a, are thus each aligned with their corresponding arterial features (i.e., vena cavae 416, 417), and not with the opposing probe. There is no teaching in Sterman that the corresponding arterial features are in alignment, and medical references suggest otherwise. If such alignment between the vena cavae were present, blood flowing from each of the vena cava would be directed toward the other vena cava. However, it is known that blood flowing into the right atrium from the superior vena cava is directed toward the atrioventricular orifice, while the inferior vena cava is directed toward the atrial septum. (Gray, Anatomy of the Human Body, Chapter V, 4b, paras. 16-17, The Heart, 1918 [Exhibit A submitted with previous Amendment].) Thus, Sterman's teaching of probes that are aligned with the different vena cava fails to teach probe ports that are aligned with each other. In that it is

known that the vena cava are NOT in alignment with each other, Sterman's teaching of probes aligned with their respective vena cava actually teaches away from probes that are aligned with each other. As the Office is aware, a reference that teaches away from a claimed invention is not an appropriate basis for a Section 103 obviousness rejection.

Claim 10 includes the distal portion being substantially perpendicular to the longitudinal axis of the probe. While the Office has asserted that Sterman depicts such a condition "dependent on where it is in the deployment process," claim 1 from which claim 10 depends includes the limitation that the probe distal portions are adjacent. Sterman provides no teaching or suggestion that a probe distal portion is perpendicular when the probe distal portions are adjacent each other.

In view of the above discussion, claims 1 and 30 as well as claims 2, 5-7, 10, 20, and 23-25 (which depend from claim 1) are allowable over Sterman, both as an anticipatory and as an obviousness reference.

In the Office Action, the Office acknowledged that Sterman et al. did not expressly disclose that the retrograde probe distal portion is positioned adjacent the antegrade distal probe, but asserted that it would have been obvious to modify Sterman et al. by altering the retrograde probe distal portion to be adjacent the antegrade probe distal portion. As noted above, however, such a change is in opposition to Sterman et al.'s purpose. Sterman et al. is an endovascular aortic partitioning system, with the partition defined by the space between the ends of the respective probes. (See, e.g., fig. 34a; col. 17, line 53 to col. 18, line 53.) Placing the respective probe ends of Sterman et al. adjacent to each other will result in no partition being created. Thus, the Office's proposed change to Sterman et al. effectively destroys Sterman et al.'s purpose.

The Office further asserted that Applicant has not asserted that the specific claimed invention provides a particular advantage, solves a stated problem, or serves a purpose different from the stated prior art. Applicant notes, however, that the current application contains numerous references to such issues, and such references are entirely different from the issues set forth in Sterman et al.

As to the particular advantage of the specific arrangement of the probes, the arrangement in the current application is for the repair of tissue. The two probes are

positioned adjacent each other in order to interact and cooperate with each other. For example, in one embodiment "the antegrade and the retrograde probe disclosed herein cooperatively interact to provide stabilizing force to the tissue interposed therebetween. For example, the cooperative action may consist of the application of force to opposing surfaces of tissue interposed between the probes, vacuum force applied by either or both probes, and mechanical retaining devices, as detailed below, disposed on either or both probes." (para. 53, lines 1-8.) This is entirely different from the cited portions of Sterman et al. (e.g., fig. 34a), which are directed toward cardiopulmonary bypass and aortic partitioning systems.

As to solving a stated problem, the problem being solved is the treatment of tissue. The "retrograde" and "antegrade" probes of Sterman et al. address the problems of aortic partitioning, not tissue treatment. Thus, the purpose of the "retrograde" and "antegrade" probes of Sterman et al. is entirely different than the current invention.

The Office alleged that "one of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the current configuration as shown by the prior art of record." This statement by the Office is not understood by Applicant. If it is the Office's position that Applicant's invention will perform equally well with the two probes positioned away from each other, then the Office's position is without merit. Upon reviewing the current application and claims, one "of ordinary skill in the art" would immediately recognize that placing the currently-claimed probes away from each other (as taught by the prior art) would prevent the desired cooperation between the two probes in stabilizing and/or repairing the tissue to be treated

In view of the above, it is clear that Sterman et al. not only fails to teach or suggest the claimed invention, but actually teaches away from the claimed invention. Accordingly, the claims are allowable over Sterman et al.

Rejections of Claims 3 and 4 under 35 USC § 103 over Sterman:

In the Office Action, the Examiner rejected claims 3 and 4 as being obvious over Sterman (U.S Patent No. 5,814,097). Applicant believes that the claims are allowable over Sterman, as set forth below.

As discussed previously in these remarks with respect to the 35 USC § 102 rejection, independent claim 1 recites a system having multiple probes, namely an antegrade probe and a retrograde probe. Additionally, claim 1 recites a portion of the retrograde probe, namely the guidewire port, as being co-aligned with the antegrade probe, and also recites the probe distal portions being adjacent to each other. By contrast, Sterman has no teaching or suggestion of using multiple probes in alignment and adjacent to each other. Accordingly, independent claim 1 is allowable over Sterman. Dependent claims 3 and 4 depend from claim 1, and are thus believed allowable over Sterman. Moreover, claims 3 and 4 each contain additional limitations that further distinguish them over Sterman.

Claim 3 recites a second guidewire, with the antegrade probe having two guidewire lumens and ports, and the retrograde probe having two guidewire lumens and ports. As discussed above with respect to claim 2, Sterman fails to depict any guidewires, and only makes passing reference that a catheter could use a guidewire. Sterman has no teaching or suggestion of a probe using multiple guidewires. Ferrari et al. similarly provides no suggestion toward such a combination of elements. While Sterman and Ferrari et al. discusses that a catheter may have multiple lumens, neither Sterman nor Ferrari et al. makes any suggestion of multiple guidewires. Without even a suggestion a multiple guidewires, it is not seen how the cited references can support a Section 103 obviousness rejection.

Claim 4 depends from claim 3 and further recites the first and second guidewires both passing through each of the probes and aligning the distal portions of the probes. While Sterman and Ferrari et al. discuss that multiple lumens may be used in a tubular body, neither Sterman nor Ferrari et al. makes any suggestion that such lumens should be used to accommodate multiple guidewires. Moreover, neither Sterman nor Ferrari et al.

provides any teaching or suggestion that multiple probes could share common guidewires, or that the common guidewires could be used to align antegrade and retrograde probes. Without even a suggestion of accommodation of multiple guidewires, or of sharing common multiple guidewires and/or using such guidewires to align respective probes, it is not seen how the cited references can support a Section 103 obviousness rejection.

In view of the above, claims 3 and 4 are believed allowable over the cited art.

Rejections of the Claims under 35 USC § 103 over Sterman and Ferrari et al.:

In the Office Action, the Examiner rejected claims 8, 9, 11, 26-28, and 37 as being obvious over Sterman (U.S. Patent No. 5,814,097) in view of Ferrari et al. (U.S. Patent No. 6,190,357). Applicant believes that the claims are allowable over Sterman and Ferrari et al., as set forth below.

As discussed previously in these remarks with respect to the 35 USC § 102 rejection, independent claim 1 recites a system having multiple probes, namely an antegrade probe and a retrograde probe. Additionally, claim 1 recites a portion of the retrograde probe, namely the guidewire port, as being co-aligned and adjacent with the antegrade probe. By contrast, neither Sterman nor Ferrari et al. provides teaching or suggestion of multiple probes that are adjacent and in alignment. Accordingly, independent claim 1 is allowable over Sterman and Ferrari et al, as are claims 8, 9, 1, and 26-28 that depend from claim 1. Claim 37 depends from claim 36, which also includes the limitation of a portion of the retrograde probe, namely the guidewire port, as being co-aligned with an antegrade probe guidewire port. Thus, claim 37 is also believed allowable over Sterman and Ferrari et al. Moreover, claims 8, 9, 11, 26-28, and 37 include further limitations to distinguish them over the art.

Claim 8 recites a vacuum lumen terminating in "at least one vacuum port at said distal portion of said antegrade probe, thereby enabling the grasping and manipulation of tissue." Claim 9 recites similar language, but with the vacuum port on the retrograde probe. No such teaching is present in Sterman or Ferrari et al. Ferrari et al. uses an

internal vacuum source only to keep its catheter in a deflated (unexpanded) state. (Ferrari et al., col. 4, lines 63-67; col. 10, lines 3-7; col. 15, line 55 to col. 16, line 6.) No teaching or suggestion is provided of a vacuum port at the distal portion of Ferrari et al., as required by claims 8 and 9. While Ferrari et al. suggests the option of using a perfusion lumen to apply the vacuum, in such an application Ferrari et al. requires the vacuum to be maintained internally, and suggests applying a one-way valve to the perfusion port to maintain the vacuum. With such a one-way valve in place, no vacuum is presented to the perfusion port. Accordingly, Ferrari et al. actually teaches away from providing a vacuum port as recited in claims 8 and 9.

In view of the above, claims 8, 9, 11, 26-28, and 37 are believed allowable over the cited art.

Rejections of the Claims under 35 USC § 103 over Sterman and Ferrari et al.:

In the Office Action, the Examiner rejected claims 8, 9, 12-19, 21, 22, and 26-52 over Sterman (U.S. Patent No. 5,814,097) in view of St. Goar et al. (U.S. Patent No. 6,629,534). Applicant believes that the claims are allowable over Sterman and Goar et al., as set forth below.

As discussed previously in these remarks with respect to the 35 USC § 102 rejection, independent claim 1 recites a system having multiple probes, namely an antegrade probe and a retrograde probe. Additionally, claim 1 recites a portion of the retrograde probe, namely the guidewire port, as being co-aligned and adjacent with the antegrade probe. By contrast, neither Sterman nor Goar et al. provides teaching or suggestion of multiple probes that are adjacent and in alignment. Accordingly, independent claim 1 is allowable over Sterman and Goar et al.

Because independent claim 1 is allowable over the cited art, claims 8, 9, 12-19, 21, 22, and 26-29 that depend therefrom are also allowable. Moreover, claims 8, 9, 12-19, 21, 22, and 26-29 include further limitations to distinguish them over the art. For example, claims 12-19 depend from claim 1, but further recite one or more tissue fasteners, tissue fastener receivers, and/or tissue fastening lumens at the distal end of a

probe. While St. Goar discloses tissue fasteners, there is no teaching or suggestion in St. Goar of using a tissue fastener in conjunction with adjacent retrograde and antegrade probes. Sterman's blood flow control systems similarly provide no teaching or suggestion of the limitations of claims 12-19.

Independent claims 30, 31, and 36 each recites a system having multiple probes, namely an antegrade probe and a retrograde probe. Additionally, claims 30, 31, and 36 each recites a portion of the retrograde probe, namely the guidewire port, as being co-aligned with the antegrade probe. As discussed previously with respect to claim 2, Sterman fails to teach such alignment. Sterman's catheters 411b and 411c, as depicted in Fig. 34a, are each aligned with their corresponding arterial features (i.e., vena cavae 416, 417), and no mention is made of alignment with the opposing probe. There is no teaching in Sterman that the corresponding arterial features are in alignment, and medical references suggest otherwise. St. Goar et al. fails to teach multiple probes, much less probes in alignment. Claim 30 also recites portions of the probes being adjacent, which is not taught by the cited art. Accordingly, independent claims 30, 31, and 36 are allowable, as are dependent claims 32-35 and 37 which depend therefrom.

Independent claim 38 recites a method of stabilizing tissue, comprising delivering antegrade and retrograde probes to the tissue from antegrade and retrograde approaches, aligning the probes longitudinally, using one or more of the probes to stabilize the tissue, and using one or more of the probes to fasten the tissue. Sterman's teaching of blood flow controlling devices, and St. Goar's teaching of a single catheter for treating tissue, provides no suggestion of multiple aligned probes, much less of the method of claim 38. Claim 38 is thus believed allowable over the cited art.

Claims 39-52 depend from claim 38, and thus are also allowable over Sterman and St. Goar et al. Claims 39-52 also include further limitations which further distinguish them over the art. For example, claim 39 recites the probes as providing support for tissue interposed therebetween. No such teaching is present in Sterman or St. Goar et al. Claim 40 recites the method as being completed without arresting the patient's heart, which is in direct contrast to the sections of Sterman cited by the Office. For example, Fig. 3 of Sterman depicts an occluding catheter "for purposes of arresting cardiac

function." (Sterman, col. 15, line 53.) Fig. 34a involves a system for use when "inducing cardioplegia in the heart." (Sterman, col. 17, line 58.) Thus, the cited portions of Sterman actually teach away from claim 40.

Claim 41 recites using the guidewire to pierce the atrial septum, advancing the guidewire to pass through the mitral valve and out an exit point, advancing the antegrade probe over the guidewire through the entry point to the mitral valve, and advancing the retrograde probe over the guidewire through the exit point to the mitral valve. While St. Goar et al. teaches using a single catheter in procedures performed through the septum, there is no teaching or suggestion in St. Goar et al. or Sterman of using antegrade and retrograde probes in combination as recited in the claims.

Claim 42 recites aligning the probes to interact to provide stabilizing support to the tissue. No such alignment or interaction is taught or suggested by St. Goar et al. or Sterman.

Claims 43-52 provide further limitations concerning the tissue and procedures involved. They also include the limitations of claim 38, namely the use of multiple probes to stabilize and fasten tissue. As discussed previously, St. Goar et al. and Sterman fail to provide such teaching. Accordingly, the claims are allowable over the cited art.

CONCLUSION

Applicant believes all claims are in condition for allowance, and respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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